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The Falls In Care Home study: a feasibility randomized controlled trial of the use of a risk assessment and decision support tool to prevent falls in care homes

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Abstract

Objective: To explore the feasibility of implementing and evaluating the Guide to Action Care Home fall prevention intervention.

Design: Two-centre, cluster feasibility randomized controlled trial and process evaluation.

Setting: Purposive sample of six diverse old age/learning disability, long stay care homes in Nottinghamshire, UK.

Subjects: Residents aged over 50 years, who had fallen at least once in the past year, not bed-bound, hoist-dependent or terminally ill.

Interventions: Intervention homes ($n=3$) received Guide to Action Care Home fall prevention intervention training and support. Control homes ($n=3$) received usual care.

Outcomes: Recruitment, attrition, baseline and six-month outcome completion, contamination and intervention fidelity, compliance, tolerability, acceptance and impact.

Results: A total of 81 of 145 (56%) care homes expressed participatory interest. Six of 22 letter respondent homes (27%) participated. The expected resident recruitment target was achieved by 76% (52/68). Ten (19%) residents did not complete follow-up (seven died, three moved). In intervention homes 36/114 (32%) staff attended training. Two of three (75%) care homes received protocol compliant training. Staff valued the training, but advised greater management involvement to improve intervention

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implementation. Fall risks were assessed, actioned and recorded in care records. Of 115 recorded falls, 533/570 (93%) of details were complete. Six-month resident fall rates were 1.9 and 4.0 per year for intervention and control homes, respectively.

Conclusions: The Guide to Action Care Home is implementable under trial conditions. Recruitment and follow-up rates indicate that a definitive trial can be completed. Falls (primary outcome) can be ascertained reliably from care records.

Keywords

Accidental falls, fall prevention intervention, nursing homes, feasibility studies, randomized controlled trial

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Introduction

Falls are three times more frequent in care home residents than in older adults living in the community and outside long-term care.^{1,2} Falls can lead to significant injury, with one in ten care home residents who fall sustaining a fracture.³ Falls account for 40% of all injury deaths in care homes.⁴ This can lead to fear of falling in care home residents, with subsequent activity restriction and associated depressive symptoms, muscular atrophy and weakness.⁵

A Cochrane systematic review⁶ found a small number of studies that suggest possible benefits from multifactorial interventions in care facilities, but the results were inconclusive. These studies involved intensive interventions organized and delivered by health service personnel, with high levels of engagement from residents. The results are difficult to extrapolate to a UK care home population, where 75% of residents are cognitively impaired⁷ and National Health Service (NHS) input to care homes is variable in structure and function, and frequently minimal, ad hoc and reactive.⁸

The Guide to Action Care Home falls prevention intervention⁹ is a multifactorial fall risk factor checklist, with suggested actions to reverse or modify fall risk factors. It was coproduced by care home staff, clinical staff and researchers. When the Guide to Action Care Home is put into practice, falls clinical specialists train small groups (four to eight) of care home staff to use the checklist in one-hour sessions. Once trained, care home staff assess each resident's falls risk, taking 15 to 20 minutes to do so. The checklist then prompts specific actions to

mitigate risk, the completion of which takes, on average, two hours. The implementation of the Guide to Action Care Home has not been subject to a large-scale robust evaluation to determine if it prevents falls, or is cost effective. To do so would require a cluster randomized controlled trial, because the intervention would need to be implemented at the whole home level to prevent cross contamination. To clarify the design parameters, estimated treatment effects and associated sample size calculations for a phase III definitive randomized controlled trial, a feasibility cluster randomized controlled trial entitled Falls In Care Homes (FICH) was conducted.

Methods

We conducted a two-centre, single-blind, feasibility, cluster randomized controlled trial with a concurrent process evaluation to explore intervention implementation and study design parameters. Ethical approval was provided by the National Research Ethics Service Committee West Midlands, Staffordshire (12/WM/0091).

As this was a feasibility study, no formal power calculation was performed. The aim was to recruit two centres and three homes in each centre. It was estimated that 60% of the population would meet eligibility criteria and provide consent. With an average of 19 residents per home, we expected a study sample of 68 resident-participants.¹⁰ The feasibility of achieving this sample size was explored

and sample size calculations for a phase III trial are presented in the discussion section.

Recruitment took place between September 2012 and February 2013. Managers of care homes listed on the Care Quality Commission¹¹ database for two centres, (1) Nottingham City and (2) Rushcliffe Borough, satisfying inclusion criteria (long stay, old age, dementia or learning disability registration, nursing/residential registration, over 10 residents, no prior experience of Guide to Action Care Home) were posted study information, expression of interest reply slips and stamped addressed envelopes. Managers who did not respond to letter invitations were telephoned to determine their level of interest and preferred recruitment procedures. Care homes were purposively selected from those who replied expressing interest, to reflect a range of ownership, size and registration.

Once six care home managers and owners had provided informed consent to study enrolment, care home staff screened residents for eligibility to take part. Eligible high-risk¹² residents (aged over 50 years, fallen at least once in the past year and not bed-bound, hoist-dependent or terminally ill) were approached by researchers and provided with a patient information leaflet and a consent form. After having adequate time to consider study information and the opportunity to discuss any concerns with a researcher, eligible residents who wished to take part in the study provided consent. Residents with mental capacity provided their own consent. Residents without mental capacity were recruited subject to family member or friend signing a consultee form indicating that the research was not contrary to their best interests.¹³

Care homes were randomized to either Guide to Action Care Home intervention group or control group (50:50 ratio) using a remote, secure, internet-based randomization system maintained and operated by the Nottingham Clinical Trials Unit. Each care home received a unique computer-generated random code. Access to the sequence was confined to the Clinical Trials Unit Data Manager (independent from the study team) who revealed allocation of each care home to NHS falls clinical specialists in accordance with the Clinical Trials Unit standard operating procedure to maintain blinding in complex

intervention trials.¹⁴ The time and details of instances of unblinding were recorded in full by a researcher.

Interventions

Care homes in the intervention group ($n=3$) received Guide to Action Care Home intervention training from falls clinical specialists as described elsewhere.⁹ Each home was provided with a Guide to Action Care Home reference manual, which reiterated the key learning outcomes and how it should be used in practice, and certificate upon training completion. Residents in the intervention group also had access to standard care.

Care homes and residents in the control group ($n=3$) had access to standard care, but no Guide to Action Care Home training or manual.

A researcher, blind to allocation, collected the following data from care home records, participants, care home staff, falls clinical specialists and the care quality commission database.

- Care home ownership, registration, specialism, number of beds, residents, staff and managers at baseline and at six months to determine stability of these characteristics over time.
- Participant age, gender, ethnicity and marital status at baseline.
- Falls rates (as these were expected to be the primary outcome measure in a definitive trial) and falls injuries were collected retrospectively for three months prior to randomization and prospectively for the six months after randomization. Falls were defined as 'unintentionally coming to rest on the ground, floor or other lower level'.¹⁵ The quality of falls recording was assessed by comparing the information collected against a validated falls incident recording form,⁹ which collated fall date, time, place, what happened and outcome.
- Performance in personal activities of daily living, using the Barthel Index^{16,17} at baseline and six months. This was self-reported by participants or proxy-reported by care home staff for participants without capacity to do so.
- The number of GP visits, hospital admissions and district nursing visits was collected from

care home records retrospectively for the three months prior to randomization and prospectively for the six months after randomization.

- The time it took to collect data for each participant.
- To estimate the cost of the Guide to Action Care Home intervention, the cost of the care home staff training was added to the cost of the time taken to deliver the intervention and the provision of the manual.
- To measure intervention delivery, contamination and usual care, researchers kept field notes, made observations and collected data from care home records at baseline and six months on falls prevention procedures, fall risk assessments and referrals to falls specialists.

After intervention implementation, a second researcher, who was not blind to allocation, completed semi-structured qualitative interviews with a diverse range of care home staff. Recruitment stopped at the point of data saturation.¹⁸ The same researcher searched care home records for evidence of Guide to Action Care Home form completion. Tolerability and compliance with the intervention among residents was considered by reviewing care home records for documented incidence of distress or refusal to accept recommendations. Falls clinical specialists who provided the Guide to Action Care Home training kept field notes and recorded the number of staff trained.

Data analysis

Counts and proportions were calculated for categorical variables and descriptive statistics for continuous variables. Statistical analyses included difference in means/medians, 95% confidence intervals, pretest/posttest, within and between group comparisons. Fall rates were calculated as the number of patient falls per 365 person days. The interview and field note data were transcribed and analysed using framework analysis.¹⁹

Results

The flow of participants and homes through the study is shown in Figure 1. Six of the 22 (27%)

letter-response interested care homes were selected for enrolment. Care home characteristics and staff turnover data are presented in Table 1. All homes remained involved in the study until completion. Of the 145 homes contacted by post, 22 (15%) expressed an interest in taking part and 59 (48%) additional homes indicated by telephone that they would have been interested in the study if they had been contacted by telephone initially.

There were 198 residents in the six care homes at the baseline data collection time point. Of these, 63 (32%) were screened as eligible to take part and 52 (82%) were recruited, with an average recruitment rate of nine participants per month. Eleven residents did not provide consent. The remaining 135 (68%) of residents were excluded from the trial on the basis that they had not fallen in the past year or were bed bound. A total of 76% of the expected sample of 68 participants was recruited. The mean age was 83 years (SD = 14), 35 (67%) were female and 51 (98%) were white British. The number of residents recruited in each home (cluster size) ranged from one to 20. A total of 22 (42%) participants independently provided consent and 30 (58%) were recruited using the consultee process. Participant characteristics are displayed in Table 2.

Baseline and outcome measures for participants in the three months before and six months after randomization can be seen in Table 3. The control and intervention groups were well balanced for demographic characteristics. A total of 75 falls were recorded in the three months before randomization.

Data could not be ascertained from 10/52 (19%) participants at six months: seven had died and three had moved outside the region. A total of 39 falls were recorded in residents' care records between recruitment and six-month follow-up. No fractures were recorded and no falls were recorded twice, with most being reported in the risk assessment sections of the care records. Quality checks on all 114 falls recorded found the date missing once, time missing 15 times, place missing 11 times, 'what happened' missing four times and outcome missing six times. There were fewer items of missing information at follow-up (10 (14%)) than at baseline (30 (41%)). At the six-month end-point,

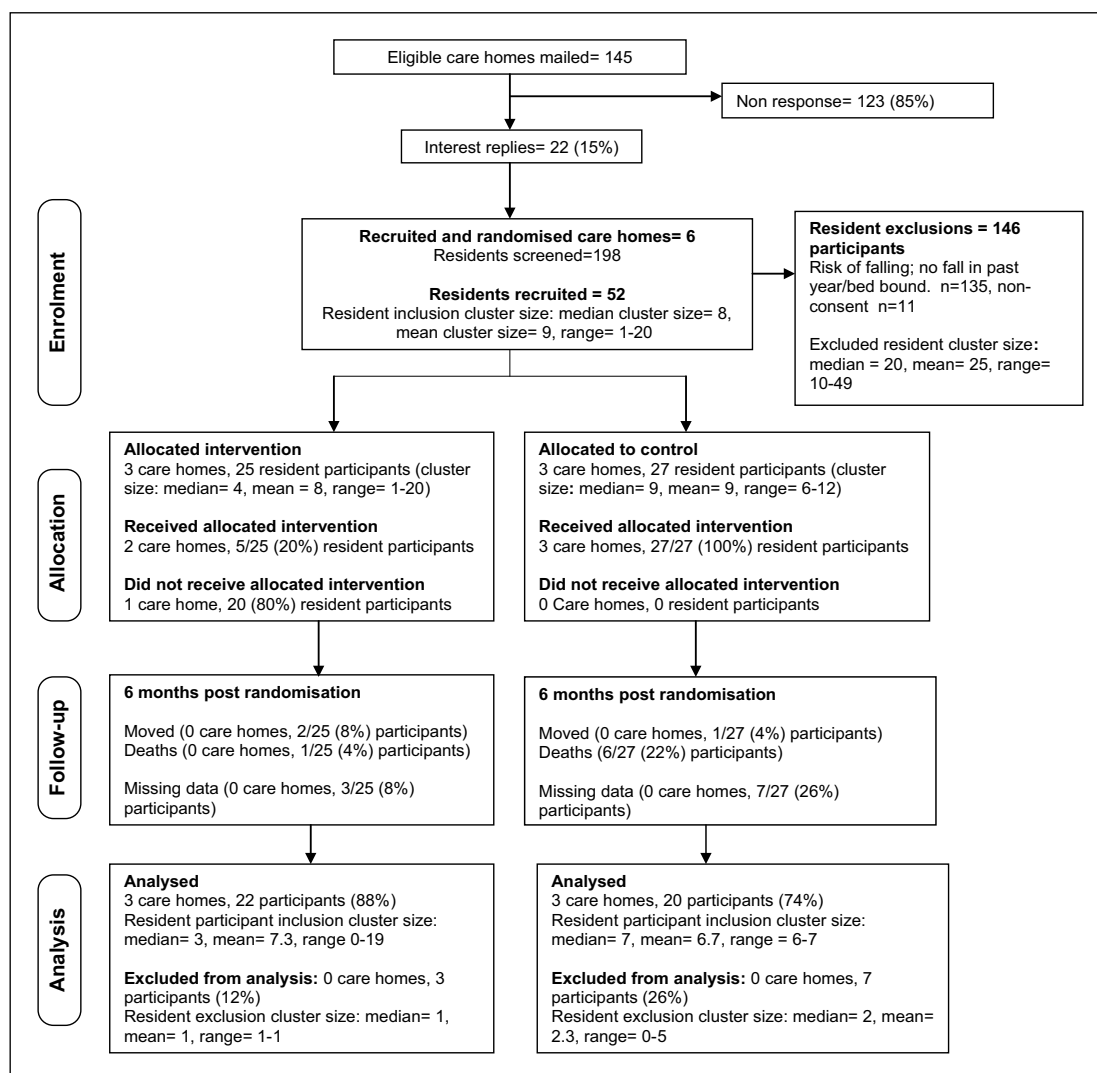


Figure 1. Consort diagram.

fall rates were lower for residents in intervention (1.9) than control homes (4) per year. Activities of daily living and health resources use data are shown in Table 3. There were nearly twice as many general practitioner visits in control homes than in intervention homes over six months of follow-up.

It took a median of 71 minutes to collect each participant's data. At analysis stage, the researcher was unblinded to group allocation in two intervention care homes when the NHS falls clinical specialist told the researcher she was visiting a care home and when the qualitative researcher told the

assessor she had interviewed staff in a home. The total cost of intervention delivery was £2111 (£84.44/resident).

Process evaluation

Interviews were conducted with 11 care staff. The data from these transcripts, field notes and narratives from care home records are presented below with quotes in *italics*.

A total of 36 out of 114 (32%) care home staff members (range 23–50%) received the Guide to

Table 1. Care home characteristics.

Care home		Intervention (n = 3)			Control (n = 3)		
		A	B	C	D	E	F
Registration	Residential	x		x			x
	Nursing				x	x	
	Dual nursing and residential		x				
Ownership	Charity	x	x				x
	Private			x	x	x	
Specialism	Old age	x	x			x	x
	Old age and learning disability			x	x		
Care Quality	All standards met	x	x		x	x	
Commission rating	Required improvement			x			x
Manager turnover (n)		0	0	1	0	0	2
Care staff turnover (n)		0	0	0	0	0	9
Total no of beds		16	74	21	16	53	40
No residents at baseline		16	74	10	16	50	32
No residents at 6 months		16	63	10	16	42	32
Baseline cluster size		1	20	4	6	12	9

Data missing (n = 1).

Table 2. Participant characteristics.

		Intervention (n = 25)	Control (n = 27)
Age (years)	Mean (SD)	84 (14.8)	82 (13.4)
	Median (IQR)	90 (80–94)	87 (67–92)
	Range	51–101	55–98
Female	n (%)	18 (72%)	17 (63%)
White British	n (%)	25 (100%)	26 (96%)
Marital status	Single n (%)	7 (28%)	7 (26%)
	Married n (%)	6 (24%)	6 (22%)
	Widowed n (%)	12 (48%)	14 (52%)
Consultee consent	n (%)	12 (48%)	18 (67%)

IQR: interquartile range.

Action Care Home training. It was delivered according to protocol (one hour) in two homes, but in the third home 17 members of staff attended for only ten minutes training. The care home that received non-protocol compliant training appeared dissatisfied and did not accept the offer of retraining. The acceptability of the training was greater in the two homes that received one hour training. Greater frequency of training and explanation of

medical terms was requested to aid understanding by one staff member. Other staff suggested the training had a positive impact on staff and participants, helping them to feel more confident, more fall risk aware and more able to transfer knowledge to other contexts without causing distress.

I found it [training] useful. Does open your eyes to little things. She mentioned something simple like

Table 3. Comparisons between baseline and six month data pre- and postintervention.

	Within group (pretest/posttest)						Between groups at 6-month end-point			
	Intervention			Control			Int	Con	Diff	(95% CI)
	B	6M	Diff	B	6M	Diff				
	n 25	n 22	(95% CI)	n 27	n 20	(95% CI)	n 22	n 20		
Falls*	Count 35	11	24 (-0.3, 1.1)	40	29	11 (-1.3, 0.7)	11	29	18 (-1.9, 0.1)	
	Rate 5.5	1.9	3.6	5.7	4.0	1.7	1.9	4.0	-2.1	
Fall injuries*	Count 16	8	8 (-0.1, 0.7)	13	6	7 (-0.4, 0.7)	8	6	2 (-0.5, 0.5)	
	Rate 2.5	1.3	1.2	1.9	0.9	1	1.3	0.9	0.4	
Barthel Index	Mean 11.9	11.3	0.6 (-0.3, 1.8)	11.0	10.1	1.10 (0.5, 2.6)	11.3	10.1	1.2 (-1.8, 4.1)	
	(SD) (4.9)	(5.1)	-0.2	(4.7)	(4.1)	0.6	(5.1)	(4.1)	1.0	
Hospital stays	Median 0	0	0 (1.0, -1.0)	0	0	0.0 (0.3, 0.3)	0	0	-0.0 (-0.8, 0.8)	
	(IQR) (0-0.5)	(0-0)	0.5	(0-0)	(0-0)	0.0	(0-0)	(0-0)	0.0	
GP visits	Mean 1.4	2.0	-0.6 (-1.7, 0.3)	2.3	3.3	-1.0 (-2.3, 0.2)	2.0	3.3	-1.3 (-2.5, -0.1)	
	(SD) (1.6)	(1.5)	0.1	(2.2)	(2.2)	0.0	(1.5)	(2.2)	-0.7	
District nurse visits	Median 0	0	-0.0 (-0.9, 0.9)	0	0.5	0.5 (0.0, 1.8)	0	0.5	-0.5 (-0.1, 0.1)	
	(IQR) (0-1)	(0-0)	1.0	(0.0-3.0)	(0-1.8)	1.2	(0-0)	(0-1.8)	-1.8	

6M: six-month assessment; B: baseline; CI: confidence interval; Con: control group; Diff: difference; Int: intervention group; IQR: interquartile range.

*Rate per year.

putting a lamp on in the bedroom at night and keeping it on, and we've done that since the training. (P26 pg 1)

Definitely made us more aware. To make sure that floors aren't mopped when residents are in. Letting the cleaners know when residents are out. Have used it with my family. Grandad had a serious fall and we took up all the rugs. (P26 pg 1)

Adherence to the Guide to Action Care Home programme proved difficult in the home for people with learning disabilities, as during the day residents attended day centres away from the home.

Our residents up to now go to a day centre for six to seven hours a day. If anything happens, it happens at the day centre. Now they just rest when they get back. (P22 pg 1)

In the other intervention homes risks and actions were documented; on occasions the Guide to Action Care Home checklist was used to guide actions, but not placed in the participants care home record. Documentation was however completed for two non-participants in one care home, after an appointment was arranged to qualitatively explore Guide to Action Care Home (GtACH) use. Care staff suggested leadership and senior involvement from managers would help increase compliance with documentation.

There was minor contamination of treatment in two homes. One had acquired a copy of the Guide to Action for Community Settings, which was designed for use in people's own homes, and one had a Guide to Action Care Home poster on the wall, which publicized the intervention. No control homes received training or the intervention manual.

The findings indicated that the usual falls prevention provision at the time of the study was a reactive fall assessment and treatment service provided by the NHS in hospital and community settings. However, there was no evidence in intervention or control homes that any participants were referred to these services over the study period. In addition, there was no evidence that care home staff received any falls prevention training in the period of the study. There was, however, evidence of fall risk assessment tools in five of the six homes. Three homes used an assessment designed

by the home manager, one used STRATIFY,²⁰ developed for use in hospitals, and one had the Guide to Action Community,²¹ initially developed for people living at home. Staff reported that they had not received training in these tools. Two of the managers, but none of the 11 staff interviewed, had heard of the Guide to Action Care Home prior to recruitment.

Discussion

The findings of this study provide recommendations for a definitive trial and suggest largely that it will be feasible to complete a definitive trial to evaluate the Guide to Action Care Home intervention. Care home staff can be trained to use the Guide to Action Care Home, and the protocol-compliant intervention was implementable and accepted by care homes, fall rates were reliably ascertained from care home records and care homes, and total recruitment and recruitment rates were proportionally high for the allocated recruitment time. This suggests recruitment targets will be met in a larger study providing similar conditions are in place. Notably, this study indicated that the intervention would need greater explanation of medical terms, more frequent training sessions and further adaptations for people living in learning disability care homes, as they frequently spend much of the day in another context, which was largely identified as external day centre attendance.

The main limitation was that the small number of homes recruited means that a number of institutional variables that might influence the success of a subsequent randomized controlled trial may have been missed. Care homes are recognized to be highly variable in terms of their organizational structure and this has been identified as a challenge to research.²² However care homes were purposively selected to reflect diverse characteristics to account for any influence that differing care home characteristics may have on the study design and Guide to Action Care Home implementation. Statistical techniques for handling heterogeneity are also well established in the randomized control literature.^{23,24} Once recruited, homes stayed in the research process and, despite care home differences, the study

design parameters and intervention were feasible. We recommend that, in a definitive trial, homes should be invited by post and by telephone. This is in line with recommended recruitment procedures²⁵ for recruiting to time and target, and to aid greater generalizability of findings. Care home characteristics, such as gender distribution, average age and average dependency were in line with national data, but staff turnover was low compared with average national Figures.²⁶ We would recommend that homes that appear to have unstable management should not be recruited into a definitive trial, and attentiveness to staff turnover as a possible confounding variable might be required as part of the analysis of data.

We recruited less than our expected resident participant sample size (76%), however the residents we did recruit had a higher falls rate than in a previous study.⁴ We recruited residents who had fallen in the past year (as documented in the available care records) and there is evidence that people who fall once are at greater risk of falling again.²⁷ Discussions with care homes regarding data collection intervals revealed that care records were archived every three months and therefore data collection intervals should be tailored accordingly for ease of data collection. Although feasible, it was a more difficult and lengthy process for care homes to identify residents following the inclusion criteria 'fallen in the past year'. Care home staff suggested that residents excluded on the basis of having not already fallen could benefit from the intervention. To overcome the screening problems and because the intervention aims to reduce the falls risk in potential fallers, we recommend that trained care home staff should provide the intervention to all residents and therefore a definitive trial should recruit all residents who are not terminally ill or receiving end-of-life care (death imminent within the next six months). By using these criteria, the fall rate will be lower and we propose that a conservative fall rate of 2.5 falls per person per year, suggested by Whitney,²⁸ be used in the control group of a definitive trial (as opposed to the 3.0 falls per year observed here). Assuming a fall rate of 2.5 falls per year, 80% power, two-sided significance level of 5%, 189 residents per

group are required to detect a 33% reduction in falls rate over a three-month period of observation. After adjusting for the clustered design, and assuming an average cluster size of 20 residents, intraclass correlation coefficient of 0.1 and an 16% attrition rate, a sample size of 1308 care home residents (654 intervention group and 654 control group) is required. If, in contrast, we take the falls rate in the intervention group from the feasibility study to estimate a sample size for the comparison of two rates at the 5% significance level (two sided), 80% power, we need 157 participants in each group before clustering is taken into account and 456 participants per group after the adjustment for clustering.²⁹

The strength of the recruitment and retention strategies employed in this study is evident in the attrition and missing data rates, which were lower than other published research performed in care home settings.³⁰ Falls were frequent and well recorded in routine care home service records. Coupled with the mandatory requirement from regulators of the UK health and care providers, this suggests care home records are an acceptable means of ascertaining fall events. However, we would recommend that only homes that can show evidence that they record falls in a systematic way before recruitment should be enrolled into a definitive trial. This method has also been used successfully in hospital settings.³¹ Although it is possible that some falls may have gone unrecorded, it should be noted that the reliability of self-reported diaries (which are usually used in falls prevention studies) in care home residents with a high prevalence of cognitive impairment⁷ is likely to be worse. It has been suggested that falls should be monitored using electronic devices, but using a subsample of participants from this study, we have previously found that accelerometers were not a feasible way to record falls or activity in this resident cohort.³² There was a general trend towards fewer falls in both intervention and control homes postintervention; this is an expected trend seen in other falls trials. Increased falls vigilance in care staff in both arms of the study is a possible contributor.³³ Service use was lower than in a recent cohort care home study⁷ and as self-completion

questionnaires have revealed large quantities of missing data in other feasibility trials,³⁴ we advise that service use data should be collected from NHS data sets. The consequence of the high degree of variability in general practitioner (GP) is unclear. We anticipate that these differences in GP support would be more evenly distributed by randomization in the greater number of homes required for a definitive trial. Any confounding variables (such as GP visit distribution) can be considered in regression analyses and evaluated upon during a process evaluation in a definitive trial. Interestingly however, fewer GP visits were evident at the six-month end-point in intervention homes.

The Guide to Action Care Home training was not delivered as per protocol in one intervention home. To enhance protocol adherence in a definitive study, we suggest that care home managers are asked to agree at the outset when and to whom the training will be provided, that refresher sessions are scheduled in advance and that protocols for inclusion of Guide to Action Care Home in care home records are agreed. Training of more staff (50–80%)³⁵ and increasing communication and coordination through additional refresher training may facilitate and strengthen staff-to-staff interactions to help overcome barriers associated with staff rotation and turnover.³⁶ Fidelity procedures to ensure strict protocol compliance should be applied, including provision of a ‘train the trainer’ manual, regular supervision and checklist monitoring. This should be evaluated as part of the concurrent process evaluation in the definitive trial. Staff felt confident to use the Guide to Action Care Home; this is especially important in contexts such as care homes whereby staff may be transient and undertrained with high demands placed upon them.³⁷ Interestingly it has been suggested that training can aid staff coping responses.³⁸ The importance of engaging the support of care home managers in implementing the training is in keeping with previous studies considering educational interventions in this setting.³⁹

Our findings regarding falls prevention usual care are in keeping with existing literature, which suggest this to be predominantly ad hoc and reactive.⁸ Some of the falls risk assessments in place in control homes had not been validated for the care

home setting and did not elicit any actions.⁴⁰ Although heterogeneous, they were sufficiently different from the coordinated, evidence-based, expert-facilitated and supported intervention represented by Guide to Action Care Home to be a feasible control intervention.

Occasions of researcher unblinding were infrequent. A definitive randomized controlled trial should incorporate robust limits on contact between ‘blinded’ and ‘non-blinded’ participants, and researchers and follow guidelines for blinding.⁴¹

In conclusion, the Guide to Action Care Home is a feasible and implementable falls prevention intervention and presents a novel tailored approach for both care home staff and care home-dwelling older adults. This study has shown that this intervention can be studied in various care home settings and is ready to be taken forward into a phase III definitive trial.

Clinical messages

- Guide to Action Care Home programme can be implemented in old age care homes.
- The integrity of protocol procedures and fidelity of controls required is supported.
- Care home records are a reliable means of recording falls.
- Preliminary signs of intervention impact have been demonstrated.

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Contributors

GMW performed data collection, analyses and writing of this article. SA designed and oversaw statistical analyses. ALG, JRFG, KR, MW and SC provided study advice,

writing and analyses. KR and MW provided the GtACH training. GA managed the trial. JD conducted interviews. WW and SK were patient and public advisors. NF recruited care homes and residents and made written contributions. PAL as Chief Investigator secured funding, designed the study, and oversaw analyses, writing of this article and all aspects of the trial.

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